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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/913,909      | 08/17/2001  | Gary J. Nabel        | NIH220.001A         | 7150             |

5318 7590 03/23/2004

NATIONAL INSTITUTES OF HEALTH  
OFFICE OF TECHNOLOGY TRANSFER  
6011 EXECUTIVE BLVD SUITE 325  
ROCKVILLE, MD 20852-3804

EXAMINER

SCHEINER, LAURIE A

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/913,909

**Applicant(s)**

NABEL ET AL

**Examiner**

Laurie A. Scheiner

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 7,8 and 14-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-13 and 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1648

Claims 1-26 are pending. Applicant's election of claims 1-6, 9-13 and 22-26 is acknowledged. Claims 7, 8 and 14-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in applicants' response of December 18, 2003.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-6, 9-13 and 22-26 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Xu et al.

Xu et al. clearly teach the expression of the transmembrane form of ebola virus glycoprotein (GP) following the construction of expression vectors containing the viral gene insert operatively linked to the CMV immediate-early region 1 enhancer and promoter. Moreover, guinea pigs challenged with doses of virus that are otherwise lethal mounted both cellular and humoral immunity to the membrane-associate GP vaccine. Xu et al. Does not differ from that which is claimed.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 6, 9-11, 13 and 22-26 are rejected under 35 U.S.C. 112, first paragraph, as being drawn to subject matter that was not described in the specification in such a way as to

Art Unit: 1648

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). The written description requirement under Section 112, first paragraph, sets forth that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the art to make and use the invention. The courts have concluded that the specification must demonstrate that the inventor(s) had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *In re Wilder, et al.*, 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Werthheim, et al.*, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Driscoll*, 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter v. Hiraga*, 6 U.S.P.Q.2d 1709 (C.A.F.C. 1988). *University of California v. Eli Lilly*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991). *Fiers v. Sugano*, 25 U.S.P.Q.2d 1601-1607 (C.A.F.C. 1993).

Applicants' disclosure fails to provide an adequate written description for the invention as broadly claimed. Essentially, the claims are drawn to vaccine or pharmaceutical composition comprising a nucleic acid molecule encoding the transmembrane form of the ebola virus glycoprotein (GP) operatively linked to a promoter. However, applicants' disclosure fails to provide adequate written support for the invention as broadly claimed. That is, applicants' claims encompass virtually any expression vector. However, the disclosure predominantly provides discussions and examples of a CMV expression vector. As such, limiting the scope of the claims commensurate with that which has been described is required by the statute. As set forth in Lockwood v. American Airlines Inc., 107 F.3d 1565, 1571-1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997):

Art Unit: 1648

It is the disclosures of the applications that count. Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification. The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. . . [A]ll that is necessary to satisfy the description requirement is to show that one is "in possession" of the invention . . . One shows that one is "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. . . Although the exact terms need not be used in haec verba, . . . the specification must contain an equivalent description of the claimed subject matter. [Citations omitted]

It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose. Each application in the chain must describe the claimed features.

The specification must contain a written description of that which is now claimed.

Fiers v. Revel, 984 F.2d 1164, 1170, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). Whether the disclosure(s) relied on "reasonably convey [ ] to the artisan that the inventor had possession at that time" of that which is now claimed is a question of fact.

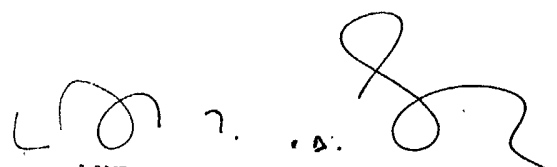
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (571) 272-0910. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Art Unit: 1648

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following central fax number: (703) 872-9306.

Laurie Scheiner/LAS  
March 12, 2004



**LAURIE SCHEINER**  
**PRIMARY EXAMINER**